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(54) Skin moisturizing microemulsions.

(5) The present invention provides microemulsions, containing moisturizing agents or sunscreens, suitable for cosmetic uses. Also disclosed are methods of moisturizing dry skin using the microemulsions containing moisturizing agents. Further, there are provided methods of potentiating the effects of macroemulsion moisturizing creams and lotions by the prior application of the described microemulsions.

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SKIN MOISTURIZING MICROEMULSIONS

An emulsion is a dispersed system containing at least two immiscible liquid phases, one of which is dispersed in the form of small droplets throughout the other, and an emulsifying agent in order to improve the stability of the system.

There are two types of emulsions depending on the droplet size of the liquids present in the emulsions. Light does not pass through macroemulsions because the droplets have average diameters of about 10 to about 1000 microns. These emulsions typically appear milky white. Microemulsions are stable systems consisting of droplets which are significantly smaller, being approximately 0.2 microns, or smaller, in diameter on the average. As such, microemulsions are translucent, and routinely transparent, in appearance.

Microemulsions are an extraordinary type of emulsion that form spontaneously. Products consisting of these systems are valued for their stability and small particle size, thus affording microemulsions a special consideration in the market place. Additional information on microemulsions and their properties may be obtained from Emulsions Emulsions and Emulsion Technology
Part I, ed. Kenneth J. Lissant, Marcel Dekker, Inc., New York, Chapter 3 "Microemulsions" (1974) and Microemulsions "1974) and Microemulsions "Decemble of the prince, and Practice ed. Leon M. Prince,

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Emulsions have a variety of uses, most notably as vehicles for the delivery of medicines. In particular, microemulsions are known to deliver pharmacologically active agents as disclosed in U.K. Patent No. 2,098,865. Microemulsions are also known to provide injectable compositions containing an anaesthetic, as disclosed in U.S. Patent No. 3,917,830, and are known as carriers for oxygen absorbing fluorinated organic compounds, as disclosed in U.S. Patent No. 3,778,381. Jayakrishnan et al. in J. Soc. Cosmet. Chem. 34, 335-350 (1983) disclose the delivery of hydrocortisone with microemulsions.

The present invention provides a method of moisturizing human skin comprising administering to said skin a microemulsion composition said composition comprising a specified moisturizing agent, as well as a microemulsion forming surfactant, a polysiloxane, and a skin humectant, and having an average droplet size in the range of about 0.001 microns to about 0.2 microns in diameter.

Another embodiment of this invention is a method of potentiating a macroemulsion moisturizing composition wherein a microemulsion composition is first applied to skin in need of moisturizing followed by application of a macroemulsion moisturizing composition. The microemulsion composition, used to potentiate the effects of a macroemulsion moisturizing composition, comprises a specified moisturizing agent, as well as a microemulsion forming surfactant, a polysiloxane,

and a skin humectant, and has an average droplet size in the range of about 0.001 microns to about 0.2 microns in diameter.

Also provided by the present invention are new microemulsion compositions. More specifically, the 5 invention provides microemulsion compositions comprising a specified moisturizing agent, as well as a microemulsion forming surfactant, a polysiloxane, and a skin humectant and having an average droplet size in the range of about 0.001 microns to about 0.2 microns in 10 diameter.

A particular composition provided is one which comprises from about 5% by weight to about 35% by weight of moisturizers, from about 20% by weight to about 80% by weight of surfactants, from about 10% by weight to about 70% by weight of polysiloxane compounds and from about 5% to about 50% by weight of skin humectants.

Finally, the present invention provides a water-in-oil microemulsion composition comprising from 20 about 1.0% by weight to about 8.0% by weight of a sunscreen, from about 15.0% by weight to about 79.0% by weight of a microemulsion forming surfactant, from about 15.0% by weight to about 79.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% 25 by weight of a skin humectant and having an average droplet size in the range of about 0.001 microns to about 0.2 microns in diameter.

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Typically, one of the two immiscibl liquids in an emulsion is aqueous while the other is an oil. Emulsions may be classified depending on which liquid forms the dispersed phase and which liquid forms the dispersion medium. An emulsion in which oil is dispersed as droplets throughout the aqueous phase is termed an oil-in-water emulsion. When water is the dispersed phase and an oil is the dispersion medium, a water-in-oil emulsion exists. Whether the aqueous phase or the oil phase becomes the dispersed phase, or is the dispersion medium, depends primarily on the emulsifying agent used and the relative amounts of the two liquid The emulsions contemplated for use in the methods of the present invention include both water-inoil microemulsions, wherein the continuous phase is oil, and oil-in-water microemulsions, wherein the continuous phase is water. The preferred microemulsions contemplated for use in the instantly claimed methods are water-in-oil microemulsions.

As noted above, the present invention provides a method of moisturizing human skin comprising administering to said skin a microemulsion composition comprising one of the compositions noted above. In particular, the method may comprise administering to the skin a composition comprising one of the following:

a) from about 1.0% by weight to about 36.0% by weight of a fatty alcohol, from about 23.5% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 28.0% by

weight of a polysiloxane, and from about 2.0% by weight to about 36.0% by weight of a skin humectant;

- b) from about 1.0% by weight to about 46.0% by weight of an animal oil, from about 14.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 35.0% by weight of a polysiloxane, and from about 2.0% by weight to about 18.0% by weight of a skin humectant;
- c) from about 1.0% by weight to about 31.0% by weight of a triglyceride, from about 37.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 35.0% by weight of a polysiloxane, and from about 2.0% by weight to about 24.0% by weight of a skin humectant;
- d) from about 1.0% by weight to about 41.0% by weight of a fatty diester, from about 23.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 2.0% by weight to about 42.0% by weight of a skin humectant;
 - e) from about 1.0% by weight to about 41.0% by weight of a branched chain fatty ester, from about 18.5% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane and from about 2.0% by weight to about 54.0% by weight of a skin humectant;
- f) from about 1.0% by weight to about 6.0% by weight of a fatty acid, from about 60.0% by weight to about 90.0% by weight of a microemulsion forming sur30 factant, from about 1.0% by weight to about 5.0% by weight of a polysiloxane, and from about 2.0% by weight to about 26.0% by weight of a skin humectant;

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- g) from about 1.0% by weight to about 41.0% by weight of a tribasic acid ester, from about 23.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 3.0% by weight to about 33.0% by weight of a skin humectant;
- h) from about 3.0% by weight to about 35.0% by weight of a vegetable oil, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant;
- i) from about 5.0% by weight to about 35.0% by weight of a long chain hydrocarbon, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant; and
- j) from about 5.0% by weight to about 35.0% by weight of a straight chain fatty ester, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant.

The present invention also provides a method of moisturizing human skin comprising administering to said skin a microemulsion comprising one of the compositions discussed above, followed by subsequent application of a macroemulsion moisturizing composition.

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Also encompassed within the present invention is a water-in-oil microemulsion composition comprising one of the following:

- a) from about 1.0% by weight to about 36.0% by weight of a fatty alcohol, from about 23.5% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 28.0% by weight of a polysiloxane, and from about 2.0% by weight to about 36.0% by weight of a skin humectant;
- b) from about 1.0% by weight to about 46.0% by weight of an animal oil, from about 14.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 35.0% by weight of a polysiloxane, and from about 2.0% by weight to about 18.0% by weight of a skin humectant;
 - c) from about 1.0% by weight to about 31.0% by weight of a triglyceride, from about 37.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 35.0% by weight of a polysiloxane, and from about 2.0% by weight to about 24.0% by weight of a skin humectant;
- d) from about 1.0% by weight to about 41.0% by weight of a fatty diester, from about 23.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 2.0% by weight to about 42.0% by weight of a skin humectant;

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-) from about 1.0% by weight to about 41.0% by weight of a branched chain fatty ester, from about 18.5% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 2.0% by weight to about 54.0% by weight of a skin humectant.
- f) from about 1.0% by weight to about 6.0% by weight of a fatty acid, from about 60.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 5.0% by weight of a polysiloxane, and from about 2.0% by weight to about 26.0% by weight of a skin humectant;
- g) from about 1.0% by weight to about 41.0% by weight of a tribasic acid ester, from about 23.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 3.0% by weight to about 33.0% by weight of a skin humectant;
- h) from about 3.0% by weight to about 35.0%

 by weight of a vegetable oil, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant;
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 i) from about 5.0% by weight to about 35.0% by weight of a long chain hydrocarbon, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant; and

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j) from about 5.0% by weight to about 35.0% by weight of a straight chain fatty ester, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant;

Another water-in-oil microemulsion of the invention comprises from about 1.0% by weight to about 8.0% by weight of a sunscreen, from about 15.0% by weight to about 79.0% by weight of a microemulsion forming surfactant, from about 15.0% by weight to about 79.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant. The composition will preferably contain from about 2.0% by weight to about 6.0% by weight of a sunscreen, from about 20.0% by weight to about 35.0% by weight of a microemulsion forming surfactant, from about 20.0% by weight to about 55.0% by weight of a polysiloxane, and from about 20.0% by weight to about 35.0% by weight of a skin humectant.

The oil-in-water and water-in-oil microemulsions employed may contain one or more ingredients which provide skin moisturizing microemulsions. These ingredients may be selected from fatty alcohols, animal oils, triglycerides, fatty diesters, branched chain fatty esters, fatty acids, tribasic acid esters, vegetable oils, long chain hydrocarbons, and straight chain fatty esters.

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Typical "fatty alcohols" useful in preparing the skin moisturizing microemulsions of the present invention contain one hydroxy group. Examples of such fatty alcohols may include behenyl alcohol, cetyl alcohol, isocetyl alcohol, isostearyl alcohol, lauryl alcohol, 2-octyldodecanol, oleyl alcohol, myristyl alcohol, and stearyl alcohol.

"Animal oils" may include, for example, cod liver oil, lanolin oil, mink oil, orange roughy oil, and shark liver oil.

Typical "triglycerides" may include caprylic/capric triglycerides, triisononanoin, triisostearin, trilaurin, trilinolein, and triolein.

Examples of typical "fatty diesters" may include dibutyl adipate, dibutyl sebacate, dicetyl adipate, diethyl sebacate, dihexyl adipate, diisocetyl adipate, diisopropyl adipate, diisopropyl dimerate, diisopropyl sebacate, diisostearyl adipate, dioctyl adipate, dioctyl sebacate, and dioctyl succinate.

"Branched chain fatty esters" may include
2-ethylhexyl isononanoate, 2-ethylhexyl myristate,
2-ethylhexyl oxystearate, 2-ethylhexyl palmitate,
2-ethylhexyl pelargonate, 2-ethylhexyl stearate,
isocetyl isodecanoate, isocetyl palmitate, isodecyl
isononanoate, isononyl isononanoate, isopropyl isostearate, isopropyl laurate, isopropyl linoleate,
isopropyl myristate, isopropyl oleate, isopropyl
palmitate, isopropyl stearate, isostearyl isostearate,
isostearyl lactate, isostearyl neopentanoate, isostearyl
palmitate, isotridecyl isononanoate, and tocopheryl
linoleate.

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Examples of acceptable "fatty acids" may include isostearic acid, lauric acid, linoleic acid, linolenic acid, and oleic acid.

Typical "tribasic acid esters" may include triisocetyl citrate, triisopropyl trilinoleate, triisostearyl trilinoleate, trilauryl citrate, and trioctyl citrate.

"Vegetable oils" may include almond oil, apricot kernel oil, avocado oil, castor oil, coconut oil, corn oil, evening primrose oil, jojoba oil, olive oil, safflower oil, sesame oil, soybean oil, and wheat germ oil.

Examples of useful "long chain hydrocarbons" may include squalane and squalene.

"Straight chain fatty esters" useful in the present invention may include lauryl lactate, lauryl myristate, lauryl palmitate, lauryl stearate, myristyl lactate, myristyl myristate, myristyl neopentanoate, myristyl propionate, myristyl stearate, oleyl erucate, oleyl linoleate, oleyl myristate, oleyl oleate, oleyl stearate, stearyl lactate, and stearyl oleate.

Preferred ingredients for use in the microemulsions of the present invention are fatty alcohols, such as isocetyl alcohol, cetyl alcohol, myristyl alcohol, and 2-octyldodecanol; animal oils, such as lanolin oil; triglycerides, such as caprylic/capric triglycerides; fatty diesters, such as diisopropyl sebacate and diisopropyl dimerate; branched chain fatty esters, such as isopropyl isostearate and isopropyl myristate; fatty acids, such as isostearic acid; and

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tribasic acid est rs, such as triisocetyl citrate. Those skilled in the art will recognize that other moisturizing agents may be used and that the moisturizers above are merely exemplary.

One or more sunscreens may be incorporated into the present microemulsions. A variety of sunscreens may be employed including the p-aminobenzoic acid derivatives such as p-(2-ethylhexyl)dimethyl-aminobenzoate, and benzophenone derivatives such as (2-hydroxy-4-methoxyphenyl)phenylmethanone. The exact amount of sunscreen employed in the present compositions will vary depending on the degree of protection desired from the sun's harmful rays.

The present composition may also contain both moisturizers and sunscreens in combination at concentrations similar to those described above when each ingredient is used alone.

A variety of microemulsion forming surfactants may be employed in the compositions of the invention. As used "microemulsion forming surfactant" is a surfact-20 ant selected from sorbitans, such as polysorbate 21 and polysorbate 60; poloxamers, such as Pluronic L-31; poloxamines, such as Tetronic 304; ethoxylated fatty alcohols, such as Brij; esters of phosphoric acid, such as PPG-10 cetyl ether phosphate and PPG-5 ceteth-10 25 phosphate; PEG castor oils, such as PEG-30 castor oil; polyoxyethylene alkylphenyl ethers, such as octoxynol-9 and nonoxynol-9; lanolin ethoxylates, such as PPG-20 lanolin ether and laneth-10 acetate; the sodium laureth sulfates; the glucose surfactants PPG-10 methyl glucose 30

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ether and PPG-20 methyl glucose ether; the sucrose ester sucrose ricinoleate; sodium lauryl sulfate; and sodium dodecyl sulfate. A particularly useful non-ionic emulsifier is Polawax or Ritachole 1000, [R.I.T.A. Chemicals, Crystal Lake, Ill.]. A preferred group of microemulsion forming surfactants are the sorbitans, the sodium laureth sulfates, sodium lauryl sulfate and sodium dodecyl sulfate.

employed in the compositions of the present invention.

These polysiloxanes may be volatile or non-volatile and include the cyclic dimethyl polysiloxanes having from three to six silicon atoms, such as cyclomethicone, as well as linear polysiloxanes having a viscosity of ten centistokes, or less, at room temperature (25°C), and mixtures thereof. A preferred polysiloxane employed in the compositions of the invention is cyclomethicone.

The compositions of the invention will also contain one or more suitable skin compatible humectants. These humectants are polar in nature and may include deionized water, as well as polyhydric alcohols such as propylene glycol, glycerine, or sorbitol or other polyhydric alcohols.

against the growth of potentially harmful microorganisms, and therefore preservatives are added as a routine.

While it is in the aqueous phase that microorganisms tend to grow, microorganisms can also reside in the oil phase. As such, preservatives which have solubility in both water and oil are preferably employed in the

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present compositions. Generally from one t nth of one percent by weight to one percent by weight of preservatives are adequate. The traditional preservatives for cosmetics and pharmaceuticals are alkyl esters of para-hydroxybenzoic acid. Other preservatives which have more recently come into use include hydantoin derivatives, propionate salts, and a variety of quaternary ammonium compounds. Cosmetic chemists are familiar with appropriate preservatives and routinely choose them to satisfy the preservative challenge test and to provide product stability. Particularly preferred preservatives for a preferred emulsion product of this invention are methyl and propyl para-hydroxybenzoates, imidazolidinyl urea, and quaternium-15. The preservatives should be selected having regard for the use of the composition and possible incompatibilities between the preservatives and the other ingredients in the emulsion.

The microemulsion compositions of the invention may also contain one or more pigments to color the composition, and a fragrance, such as Firmenich and Co. 66.001/NY/G fragrance oil, to make the composition soothing to the olfactory system. The amount of these ingredients present in the composition will depend on the specific effect desired.

The compositions of the invention may be prepared by procedures well known to formulation chemists. Typically, an oil phase is prepared by combining all hydrophobic components, as well as the water-insoluble solids, in a container and heating the resulting mixture under agitation until all the ingredients are dissolved. In a separate container, an agu ous phase is prepared by combining all of the hydrophilic components, as well as the oil-insoluble solids, and heating the resulting mixture under constant stirring until the mixture is homogeneous. The microemulsion forming surfactant, or surfactants, are separately combined and mixed until homogeneous, and heat may be applied if necessary. The three phases thus prepared are combined and stirred until homogeneous and the solution becomes clear when allowed to stand at room temperature. The composition is finally allowed to stand for approximately 24 hours in order for the composition to achieve equilibrium. The composition may be transferred to appropriate containers for storage until needed for application to individuals in need of a microemulsion of the invention.

As noted above, the compositions of the invention are translucent, and typically transparent because the average droplet size of a microemulsion being very small (compared to the macroemulsion average droplet size of about 10 microns or more in diameter) will not reflect light. As such, the compositions of the invention will have a droplet size in the range of about 0.001 microns to about 0.2 micron in diameter, more typically in the range of about 0.001 microns to about 0.14 microns in diameter.

The compositions of the invention are useful for a variety of purposes, especially for protecting the skin's surface from, for example, the sun, wind, or rain. The present microemulsions are particularly well suited for moisturizing skin and this is the primary use

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contemplated for th microemulsions. To assist in protecting skin from the sun, a sunscreen may be incorporated into the microemulsions of the invention.

In addition, the microemulsion compositions employed in the present invention provide superior results when applied to skin since they leave little residue on the surface of the skin following their application. Further, the compositions are generally not irritating to the skin when formulated with the proper balance of nonionic surfactants.

It is important from a commercial standpoint that the compositions of the invention remain stable over a range of temperatures and under various conditions. For example, these compositions may be used under warm, humid conditions in the summer, or under cold, dry conditions in the winter. While such stability is important from an esthetic point of view, this generally does not substantially affect the operability of the microemulsions of the invention.

As noted above, the microemulsions described are useful in moisturizing human skin. Therefore, one embodiment of the present invention is a method of moisturizing human skin comprising administering to the skin a microemulsion as described.

The particular quantity of microemulsion administered, of course, will be determined by the particular circumstances surrounding its use, including the microemulsion administered, the condition of the skin, the age of the user, the degree of moisturization desired, and similar considerations. The microemulsions

are administered transdermally. Typically, a single application of the microemulsion will be applied topically to cover adequately the affected area of the skin. Subsequent applications may be made as needed to maintain the desired level of moisturization of the skin.

The microemulsions employed in the present invention are particularly important because of their ability to increase the rate of penetration of the incorporated moisturizing agents into the areas of skin in need of moisturizing. Tests have been conducted in laboratory animals comparing microemulsions containing a radiolabeled ingredient with commercially available macroemulsion moisturizers. These tests have shown that greater amounts of the radiolabeled material reach the dermis and epidermis of the skin faster for the microemulsion moisturizer. Tests on laboratory animals have indicated also that the microemulsions employed in the present invention cause epidermal thickening. Epidermal thickening can lead to a highly desirable increase in skin resilience and elasticity.

Also discovered is that the present microemulsions have the ability to potentiate the effect of
subsequently applied macroemulsion moisturizers. By
first applying to the skin a microemulsion of the
invention, followed by application of a macroemulsion
moisturizing composition, the microemulsion has been
shown to enhance the penetration of the subsequently
applied moisturizing composition. Thus, the rate of
penetration of a particular macroemulsion moisturizing
composition is increased as compared to the rate of

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penetration of that moisturizing composition alon. As such, the present invention provides, as an additional embodiment, a method of potentiating a macroemulsion moisturizing composition wherein a microemulsion is first applied to the skin followed by the application of a macroemulsion moisturizing composition.

Macroemulsion moisturizing compositions are well known in the art. As described previously a macroemulsion consists of an oil-in-water or water-in-oil emulsion wherein the average droplet size is from about 10 microns to about 1000 microns in diameter. Such emulsions exist in both lotion and cream form and are often opaque or white in appearance due to the larger droplet size. Macroemulsion moisturizing compositions encompassed within the presently disclosed potentiation method are emulsions of the above size which have a moisturizing effect and will be familiar to those skilled in the art.

The following non-limiting Examples illustrate formulations employed in the invention, and methods for their preparation.

An oil phase was prepared by combining 1000 g (25.0%) of Silicone 344 Fluid (cyclomethicone from Dow 5 Corning Corp., Midland, Michigan), 788 g (19.7%) of Robane (squalane from Robeco Chemicals, Inc., New York, New York), 80 g (2.0%) of Polawax or Ritachol 1000 (non-ionic emulsifier from R.I.T.A. Chemicals Corp., Crystal Lake, Ill.), and 120 g (3.0%) of isopropyl myristate and stirring the resulting mixture under heat 10 until homogeneous. To the oil phase was added 6 g (0.15%) of methylparaben and 6 g (0.15%) of propylparaben and the resulting mixture was heated, at about 50°C, until the two paraben derivatives were dissolved. 15 In a separate container a water phase was prepared by dissolving 8 g (0.2%) of Germall 115 (imidazolidinyl urea from Sutton Laboratories, Inc., Chatham, New Jersey) in a solution of 80 g (2.0%) of glycerine and 912 g (22.8%) of deionized water. The water and oil 20 phases were combined. To the resulting mixture was added 1000 g (25.0%) of Tween 21 (polysorbate 21 from ICI Americas, Inc., Wilmington, Delaware) at room temperature and the mixture was allowed to equilibrate overnight prior to transferring the resulting water-in-25 oil microemulsion composition into appropriate containers for storage.

	Phase	Ingredient	Weight (g)	Weight %
	Oil	Silcone 344 Fluid	800	20.0
		Robane .	588	14.7
10		Ritachol 1000	80	2.0
		isopropyl myristate	120	3.0
		jojoba oil	400	10.0
15	Water	deionized water	832	20.8
		glycerine	160	4.0
		methylparaben	6	0.15
		propylparaben	6	0.15
20		Germall 115	8	0.2
	Surfactant	T-Maz 21 (poly- sorbate 21 from Mazer Chemical: Inc., Gurnee,		25.0
25		Illinois)		

Exampl 3

A water-in-oil microemulsion of the invention was prepared containing the following ingredients

5 according to the general procedure of Example 1.

	Phase	Ingredient	Weight (g)	Weight %
	Oil	Silcone 344 Fluid	200	20.0
•		Robane	129	12.9
10	•	jojoba oil	100	10.0
		isopropyl myristate	30	3.0
		propylparaben	1	0.1
		propylene glycol	20	2.0
15		myristyl alcohol	10	1.0 ·
		cetyl alcohol	6	0.6
		polysorbate 60	4	0.4 .
20	Water	deionized water	244	24.4
20		Germall 115	3	0.3
		methylparaben	3	0.3
25	Surfactant	polysorbate 21	250	25.0

Following the procedure outlined in Example 3, the following ingredients were formulated to provide a water-in-oil microemulsion of the invention.

	Phase	Ingredient	Weight (g)	Weight %
	Oil	Silcone 344 Fluid	008 £	20.0
	_	Robane	594	14.85
10		isopropyl myristate	120	3.0
		jojoba oil	400	10.0
	Water	glycerine	80	2.0
15		deionized water	904	22.6
		propylparaben	6	0.15
		methylparaben	6	0.15
		Germall 115	8	0.20
20	Surfactant	sodium		
		dodecyl sulfate	2	0.05
		T-Maz 21	1080	27.0

	<u>Phase</u>	Ingredient	Weight (g)	Weight %
	Oil	cyclomethicone	24.22	24.22
		isocetyl alcohol	31.98	31.98
10		propyl paraben	0.1	0.1
	Water	deionized water	16.98	16.98
		propylene glycol	1.41	1.41
15		Dowicil 200 (quaternium-15)	0.2	0.2
		methyl paraben	0.1	0.1
	Surfactant	polysorbate 21	23.15	23.15
		polysorbate 60	0.37	0.37
20		myristyl alcohol	0.93	0.93
		cetyl alcohol	0.56	0.56

Example 6

	Phase	Ingredient	Weight (g)	Weight %
	oil	cyclomethicone	15.09	15.09
		lanolin oil	19. 9 2	19.92
10		propyl paraben	0.10	0.10
	Water	deionized water	13.45	13.45
		propylene glycol	1.13	1.13
		Dowicil 200	0.20	0.20
15		methyl paraben	0.10	.0.10
	Surfactant	polysorbate 21	46.30	46.30
		polysorbate 60	0.74	0.74
	•	myristyl alcohol	1.85	1.85
20		cetyl alcohol	1.12	1.12

Example 7

	<u>Phase</u>	Ingredient	Weight (g)	Weight %
	Oil	cyclomethicone	18.96	18.96
10		caprylic/capric triglyceride	25.04	25.04
		propyl paraben	0.10	0.10
	Water	deionized water	9.76	9.76
	•	propylene glycol	0.83	0.83
15		· Dowicil 200	0.20	0.20
		methyl paraben	0.10	0.10
	Surfactant	polysorbate 21	41.67	41.67
		polysorbate 60	0.67	0.67
20		myristyl alcohol	1.67	1.67
		cetyl alcohol	1.00	1.00

	Phase	Ingredient V	Weight (g)	Weight %
	Oil	cyclomethicone	21.12	21.12
		diisopropyl sebacat	te 27.88	27.88
10		propyl paraben	0.10	0.10
	Water	deionized water	19.02	19.02
		propylene glycol	1.58	1.58
		Dowicil 200	0.20	0.20
15		methyl paraben .	0.10	0.10
	Surfactant	polysorbate 21	27.78	27.78
		polysorbate 60	0.44	0.44
		myristyl alcohol	1.11	1.11
20		cetyl alcohol	0.67	0.67

	Phase	Ingredient	Weight (g)	Weight %
	Oil	cyclomethicone	17.76	17.76
		isopropyl isosteara	te 23.44	23.44
10		propyl paraben	0.10	0.10
	Water	deionized water	30.85	30.85
	·	propylene glycol	2.54	2.54
		Dowicil 200	0.20	0.20
15		methyl paraben	0.10	0.10
	Surfactant	polysorbate 21	· 23.15	23.15
		polysorbate 60	0.37	0.37
		myristyl alcohol	0.93	0.93
20	• •	cetyl alcohol	0.56	0.56

	Phase	Ingredient	Weight (g)	Weight %
	Oil	cyclomethicone	4.56	4.56
	OII	isostearic acid	6.02	6.02
10		propyl paraben	0.10	0.10
	Water	deionized water	17.7	17.7
	Hacci	propylene glycol	1.47	1.47
		Dowicil 200	0.20	0.20
15		methyl paraben	0.10	0.10
	Surfactant	polysorbate 21	64.68	64.68
	Darracount	polysorbate 60	1.03	1.03
		myristyl alcohol	2.58	2.58
20		cetyl alcohol	1.56	1.56

	<u>Phase</u>	<u>Ingredient</u>	Weight (g)	Weight %
	Oil	cyclomethicone	21.12	21.12
		triisocetyl citrate	27.88	27.88
10		propyl paraben	0.10	0.10
	Water	deionized water	19.02	19.02
		propylene glycol	1.58	1.58
		Dowicil 200	0.10	0.10
15		methyl paraben	0.20	0.20
	Surfactant	polysorbate 21	27.78	27.78
		polysorbate 60	0.44	0.44
		myristyl alcohol	1.11	1.11
20		cetyl alcohol	0.67	0.67

Example 12

	Phase	Ingredient	Weight (g)	Weight %
	oil	cyclomethicone	21.03	21.03
		diisopropyl dimerate	27.77	27.77
10		propyl paraben	0.10	0.10
	Water	deionized water	23.82	23.82
		propylene glycol	1.97	1.97
		Dowicil 200	0.20	0.20
15	·	methyl paraben	0.10	0.10
	Surfactant	polysorbate 21	23.15	23.15
		polysorbate 60	0.37	0.37
		myristyl alcohol	0.93	0.93
20		cetyl alcohol	0.56	0.56

An oil phase was prepared by combining 0.49 g (0.49%) of cetyl alcohol, 0.81 g (0.81%) of myristyl alcohol, 0.15 g (0.15%) of methylparaben, 0.15 g (0.15%) 5 of propylparaben, 0.32 g (0.32%) of polysorbate 60, 2.17 g (2.17%) of isocetyl alcohol, and 2.17 g (2.17%) of 2-octyldodecanol, and heating the resulting mixture with agitation until all solids had dissolved. remainder of the oil phase ingredients were added; 10 25.93 g (25.93%) cyclomethicone, 12.08 g (12.08%) squalane, 3.12 g (3.12%) jojoba oil, 3.12 g (3.12%) isopropyl myristate, 3.12 (3.12%) p-(2-ethylhexyl)dimethylaminobenzoate, and the mixture stirred until To the oil phase was added 21.66 g homogeneous. . 15 (21.66%) polysorbate 21 and 0.25 g (0.25%) fragrance oil and the resulting mixture stirred until homogeneous. A water phase was prepared in a separate container by combining 18.79 g (18.79%) deionized water, 0.20 g (0.20%) quaternium-15, 0.22 g (0.22%) sodium lauryl 20 sulfate, 0.83 g (0.83) butylene glycol, 1.00 g (1.00%) 2-phenoxyethanol, 1.25 g (1.25%) propylene glycol, and 2.17 g (2.17%) sodium laureth sulfate (30% by weight in water), and heating the resulting mixture under agitation until homogeneous. The water phase was added to 25 the previously prepared mixture and the resulting composition was stirred until homogeneous. Once the mixture was homogeneous the composition was stored at room temperature until ready for use.

Two water-in-oil microemulsions of the invention were prepared containing a sunscreen. The preparation of these compositions is illustrated below.

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Example 14

An oil phase was prepared by combining 260 g (26.0%) of Silicone 344 Fluid, 157 g (15.7%) of Robane, 30 g (3.0%) of isopropyl myristate, 30 g (3.0%) of Escalol 507 (p-(2-ethylhexyl)dimethylaminobenzoate) and 20 g (2.0%) of (2-hydroxy-4-methoxyphenyl)phenylmethanone, and heating the resulting mixture with agitation until homogeneous. To the oil phase was added 1.5 g (0.15%) of propylparaben, and the resulting mixture was stirred until the propylparaben was dissolved. A water phase was prepared in a separate container by combining 248 ml (24.8%) of water and 1.5 g (0.15%) of methylparaben with 2.0 g (0.2%) of Germall 115 and heating the resulting mixture under agitation until homogeneous. The oil and water phases were combined and 250 g (25.0%) of T-Maz 21 was added thereto. The resulting composition was stirred until homogeneous and stored at room temperature until ready for use.

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Example 15

An oil phase was prepared by combining 1040 g
(26.0%) of Silicone 344 Fluid, 628 g (15.7%) of Robane,
120 g (3.0%) of isopropyl myristate, 120 g (3.0%) of
Escalol 507 and 80 g (2.0%) of (2-hydroxy-4-methoxyphenyl)phenylmethanone in a suitable container. The
mixture was heated and stirred until homogeneous. To
the oil phase was added 6 g (0.15%) of methylparaben and
30 6 g (0.15%) of propylparaben with stirring until the
mixture was homogeneous. A water phase was prepared in

a s parate container by combining 992 g (24.8%) of water with 8 g (0.2%) of Germall 115 and 8 g (0.2%) of sodium dodecyl sulfate. The oil and water phases were combined and 992 g (24.8%) of Tween 21 was added thereto. The mixture was stirred until homogeneous and stored at room temperature until ready for use.

Certain of the compositions of the invention were tested to demonstrate efficacy as moisturizing The test was conducted on dry skin, and the compositions to be tested were used over a 3-week 10 period, followed by a two-week regression period. Thirty-two subjects were used in the study to test the efficacy of the formulations. Subjects were divided into two groups of 16 and each member of one group randomly received the formulation of Example 1 on one 15 leg and the formulation of Example 2 on the other leg. In the second group subjects randomly received the formulation of Example 4 on one leg. The study was carried out for seven weeks. For the first two weeks, skin was allowed to dry. For the next three weeks 20 treatment was conducted, and the final two weeks were a regression period. Subjects with obvious skin conditions, extensive varicose veins, deep suntans, or conditions on their legs other than dry skin were excluded from the study. Subjects ranged in age from 18 25 to 45 years. Evaluations were performed blind by the same evaluator, when possible. Evaluations were done 7, 5 and 3 days before application, the initial day of treatment prior to application, and 1, 2, 3, 4, 7, 9, 10, 11, 15, 16, 17, 18, 21, 22, 23, 24, 25, 28, 30, 32 30 and 35 days after the initial application. Test formu-

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lations were appli d to the leg(s) twice each day for three weeks, once in the morning in the laboratory and each evening at home on weekdays. All week-end applications (morning and evening) were performed at home. No other skin moisturizers except the test formulations were allowed during the course of the study. In addition, the subjects were not allowed to swim or sunbathe. Showers, baths, and water contact to the legs were also not allowed the mornings that evaluations were performed.

Evaluations were performed according to the following scale:

- 0 = smooth, no evidence of dryness
- 1 = slightly dry skin
- 2 = moderately dry skin; peeling
- 3 = severely dry skin; flaking, peeling
- 4 = extremely dry skin; flaking, peeling and/or
 fissures
- Results (mean dryness scores) of each of the formulations were compared to the untreated control and to the positive control groups. In addition, each product was evaluated for significant change from day 0 for each evaluation day in the study. This data is presented below in Table I as the average of the 16 subjects employed.

Table I
Moisturization Study

5	Days After First Application	Formula 1	tion of Ex	ample No.
	0	3.0	3.0	3.0
	1	2.0	1.8	2.3
	2	0.9	0.8	1.3
10	3	0.3	0.4	0.8
	4	0.5	0.3	0.6
	7	0.1	0.1	0.7
	9	0.5	0.4	0.4
	10	0.3	0.2	0.5
15	11	0.1	0	0.5
	15	0.9	0.7	1.3
	16	0.2	0.2	0.8
	17	0.2	0.3	0.4
	18	0.1	0.1	0.3
20	21	0.1	0.1	0.3
	22	0.5	0.3	0.9
	23	0.2	0.3	1.3
	24	0.5	0.3	1.1
25	25	0.5	0.4	1.1
	28	0.9	0.6	1.6
	30	1.1	1.0	1.9
	32	1.8	1.8	2.3
	35	2.4	2.4	2.8
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The data generated from the preceding experiment indicate the effectiveness of the formulae of Examples 1 and 2 as moisturizers. The formula of Example 4 demonstrated moderate effectiveness as a moisturizer.

CLAIMS

- 1. A skin moisturizing microemulsion composition which comprises a moisturizer, a microemulsion forming surfactant, a polysiloxane compound, a skin humectant and having an average droplet size in the range of about 0.001 microns to about 0.2 microns in diameter.
- 2. A skin moisturizing microemulsion

 composition as claimed in Claim 1 which comprises from about 5% by weight to about 35% by weight of moisturizers, from about 20% by weight to about 80% by weight of surfactants, from about 10% by weight to about 70% by weight of polysiloxane compounds and from about 5% to about 50% by weight of skin humectants.
 - 3. A moisturizing composition as claimed in Claims 1 or 2 which additionally comprises from about 0.1% by weight to about 1.0% by weight of preservatives.
- 4. A moisturizing composition as claimed in 20 any one of Claims 1 to 3 consisting of:

	<u>Ingredient</u>	Weight %
	cyclomethicone	25.0
	squalane	19.7
	Polawax	2.0
25	isopropyl myristate	3.0
	water	22.8
	glycerine	2.0
	polysorbate 21	25.0
	methylparaben	0.15
30	propylparaben	0.15
•	imidazolidinyl urea	0.2

5. A composition as claimed in any one of Claims 1 to 3 consisting of:

	Ingredient	Weight %
	cyclomethicone	20.0
5	squalane	14.7
	Polawax	2.0
	isopropyl myristate	3.0
	jojoba oil	10.0
	water	20.8
10	glycerine	4.0
	polysorbate 21	25.0
	methylparaben	0.15
	propylparaben	0.15
	imidazolidinyl urea	0.2

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6. A composition as claimed in any one of Claims 1 to 3 consisting of:

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	Ingredient	Weight %
	cyclomethicone	20.0
20	squalane	12.9
	isopropyl myristate	3.0
	jojoba oil	10.0
	water	24.4
	propylene glycol	2.0
25	polysorbate 21	25.0
	myristyl alcohol	1.0
	cetyl alcohol	0.6
	polysorbate 60	0.4
	methylparaben	0.3
30	propylparaben	0.1
	imidazolidinyl urea	0.3

7. A composition as claim d in any one of Claims 1 to 3 consisting of:

	Ingredient	Weight %
	cyclomethicone	20.0
5	squalane	14.85
	isopropyl myristate	3.0
	jojoba oil	10.0
	water	22.6
•	glycerine	2.0
10	polysorbate 21	27.0
	sodium dodecyl sulfate	0.05
	methylparaben	0.15
	propylparaben	0.15
	imidazolidinyl urea	0.2

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- 8. A microemulsion composition as claimed in Claim 1 also comprising a suncreen.
- 9. A microemulsion composition of Claim 8 comprising from about 1% by weight to about 8% by weight of a suncreen, from about 15% by weight to about 79% by weight of a polysiloxane compound, from about 15% by weight to about 79% by weight of a microemulsion forming surfactant, and from about 5% to about 50% by weight of skin humectants.
- 25 10. A composition as claimed in Claim 9 comprising as additional ingredients from about 0.1% by weight to about 1.0% by weight of preservatives.

11.	A	composition	of	claim	10	consisting	of	:
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	Ingredient	Weight %
	cyclomethicone	26.0
	squalane	15.7
5	isopropyl myristate	3.0
	<pre>p-(2-ethylhexyl)- dimethylaminobenzoate</pre>	3.0
	benzophenone-3	2.0
	water	24.8
10	polysorbate 21	25.0
	methylparaben	0.15
	propylparaben	0.15
•	imidazolidinyl urea	0.2

12. A composition as claimed in Claim 10 consisting of:

	Ingredient	Weight %
	cyclomethicone	26.0
	squalane	15.7
20	isopropyl myristate	3.0
	<pre>p-(2-ethylhexyl)- dimethylaminobenzoate</pre>	3.0
	benzophenone-3	2.0
	water	24.8
25	polysorbate 21	24.8
	sodium dodecyl sulfate	0.2
	methylparaben	0.15
	propylparaben	0.15
	imidazolidinyl urea	0.2

- 13. A moisturizing microemulsion composition as claimed in Claim 1 which comprises:
- a) from about 1.0% by weight to about 36.0% by weight of a fatty alcohol, from about 23.5% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 28.0% by weight of a polysiloxane, and from about 2.0% by weight to about 36.0% by weight of a skin humectant;
- b) from about 1.0% by weight to about 46.0% by 10 weight of an animal oil, from about 14.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 35.0% by weight of a polysiloxane, and from about 2.0% by weight to about 18.0% by weight of a skin humectant;
- 15 c) from about 1.0% by weight to about 31.0% by weight of a triglyceride, from about 37.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 35.0% by weight of a polysiloxane, and from about 2.0% by weight 20 to about 24.0% by weight of a skin humectant;
 - d) from about 1.0% by weight to about 41.0% by weight of a fatty diester, from about 23.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 2.0% by weight
- 25 to about 42.0% by weight of a skin humectant;

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- e) from about 1.0% by weight to about 41.0% by weight of a branched chain fatty ester, from about 18.5% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 2.0% by weight to about 54.0% by weight of a skin humectant;
- f) from about 1.0% by weight to about 6.0% by weight of a fatty acid, from about 60.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 5.0% by weight of a polysiloxane, and from about 2.0% by weight to about 26.0% by weight of a skin humectant;
- g) from about 1.0% by weight to about 41.0% by weight of a tribasic acid ester, from about 23.0% by weight to about 90.0% by weight of a microemulsion forming surfactant, from about 1.0% by weight to about 31.0% by weight of a polysiloxane, and from about 3.0% by weight to about 33.0% by weight of a skin humectant;
- h) from about 3.0% by weight to about 35.0%

 20 by weight of a vegetable oil, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant;
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 i) from about 5.0% by weight to about 35.0%
 by weight of a long chain hydrocarbon, from about 20.0%
 by weight to about 80.0% by weight of a microemulsion
 forming surfactant, from about 10.0% by weight to about
 70.0% by weight of a polysiloxane, and from about 5.0%
 by weight to about 50.0% by weight of a skin humectant; or

j) from about 5.0% by weight to about 35.0% by weight of a straight chain fatty ester, from about 20.0% by weight to about 80.0% by weight of a microemulsion forming surfactant, from about 10.0% by weight to about 70.0% by weight of a polysiloxane, and from about 5.0% by weight to about 50.0% by weight of a skin humectant.

14. A composition as claimed in claim 13 which consists of:

10	Ingredient	Weight %
	cyclomethicone	25.93
	<pre>p-(2-ethylhexyl)- dimethylamino- benzoate</pre>	3.12
15	fragrance oil	0.25
	squalane	12.08
	jojoba oil	3.12
	isopropyl myristate	3.12
	myristyl alcohol	0.81
20	cetyl alcohol	0.49
	isocetyl alcohol	2.17
	2-octyldodecanol	2.17
	deionized water	18.79
	propylene glycol	1.25
25	butylene glycol	0.83
	polysorbate 21	21.66
	polysorbate 60	0.32
30	sodium laureth sulfate (30% by weight in water)	2.17
	sodium lauryl sulfate	0.22
	2-phenoxyethanol	1.00
	quaternium-15	0.20
	methyl paraben	0.15
35	· propyl paraben	0.15

15. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
	cyclomethicone	24.22
5	isocetyl alcohol	31.98
	myristyl alcohol	0.93
	cetyl alcohol	0.56
	deionized water	16.98
	propylene glycol	1.41
10	polysorbate 21	23.15
	polysorbate 60	0.37
	propyl paraben	0.1
	quaternium-15	0.2
	methyl paraben	0.1

16. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
	cyclomethicone	15.09
20	lanolin oil	19.92
	myristyl alcohol	1.85
	cetyl alcohol	1.12
	deionized water	13.45
	propylene glycol	1.13
25	polysorbate 21	46.30
	polysorbate 60	0.74
	propyl paraben	0.10
	quaternium-15	0.20
	methyl paraben	0.10
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17. A composition as claimed in Claim 13 consisting of:

Ingredient	Weight %
cyclomethicone	18.96
caprylic/capric triglyceride	25.04
myristyl alcohol	1.67
cetyl alcohol	1.00
deionized water	9.76
propylene glycol	0.83
polysorbate 21	41.67
polysorbate 60	0.67
propyl paraben	0.10
quaternium-15	0.20
methyl paraben	0.10
	cyclomethicone caprylic/capric triglyceride myristyl alcohol cetyl alcohol deionized water propylene glycol polysorbate 21 polysorbate 60 propyl paraben quaternium-15

18. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
20	cyclomethicone	21.12
	diisopropyl sebacate	27.88
	myristyl alcohol	1.11
	cetyl alcohol	0.67
	deionized water	19.02
25	propylene glycol	1.58
	polysorbate 21	27.78
	polysorbate 60	0.44
	propyl paraben	0.10
	quaternium-15	0.20
30	methyl paraben	0.10

19. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
	cyclomethicone	17.76
5	isopropyl isostearate	23.44
	myristyl alcohol	0.93
	cetyl alcohol	0.56
	deionized water	~30.85
	propylene glycol	2.54
10	polysorbate 21	23.15
	polysorbate 60	0.37
	propyl paraben	0.10
	quaternium-15	0.20
	methyl paraben	0.10

20. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
	cyclomethicone	4.56
20	isostearic acid	6.02
	myristyl alcohol	2.58
	cetyl alcohol	1.56
	deionized water	17.7
	propylene glycol	1.47
25	polysorbate 21	64.68
	polysorbate 60	1.03
	propyl paraben	0.10
	quaternium-15	0.20
	methyl paraben	0.10

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21. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
	cyclomethicone	21.12
5	triisocetyl citrate	27.88
	myristyl alcohol	1.11
	cetyl alcohol	0.67
	deionized water	19.02
	propylene glycol	1.58
10	polysorbate 21	27.78
	polysorbate 60	0.44
	propyl paraben	0.10
	.quaternium-15	0.10
	methyl paraben	0.20

22. A composition as claimed in Claim 13 consisting of:

	Ingredient	Weight %
	cyclomethicone	21.03
20	diisopropyl dimerate	27.77
	myristyl alcohol	0.93
	cetyl alcohol	0.56
	deionized water	23.82
	propylene glycol	1.97
25	polysorbate 21	23.15
	polysorbate 60	0.37
	propyl paraben	0.10
	quaternium-15	0.20
	methyl paraben	0.10
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- 23. A method for moisturizing skin which comprises administering to said skin a microemulsion composition as claimed in any one of Claims 1 to 22.
- 24. A method as claimed in Calim 23 in which a macroemulsion moisturizing composition is subsequently applied to the skin.



EUROPEAN SEARCH REPORT

Application number

EP 86 30 8852

Category		h indication, where appropriate, ant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CI 4)
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	DOCUMENTS CONSIL				Page 2
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